

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph beginning on page 2, line 25, with the following amended paragraph:

The present invention relates to a novel method for treatment and prophylaxis of such enteric infections, which is both safe and effective. This is achieved by using IgY directed against enteric bacteria, and in particular against ~~Enterobacter cloacae~~ Enterobacter cloacae, and ~~Candida albicans~~ Candida albicans, which has been obtained from the egg yolk of birds, that have been hyperimmunised with an antigen (=microbe) in order to stimulate the production of immunoglobulines (IgY) against this microbe.

Please replace the paragraph beginning on page 3, line 23, with the following amended paragraph:

The present invention relates to prophylaxis or therapy of all kind of infections in newborn infants, prematurely born infants, and infants having an immature immune system, patients suffering from temporary immunodeficiency and immunodeficiency diseases such AIDS. The infection can be any infection caused by an antigen such as bacterium, virus, fungus or parasite, that is infections in general, preferably bacterial infections, more preferably enteric infections and most preferably infections caused by

~~Enterobacter cloacae~~ Enterobacter cloacae and ~~Candida albicans~~  
Candida albicans.

Please replace the paragraph beginning on page 4,  
line 16, with the following amended paragraph:

The present invention is based on the discovery that  
~~anti-Enterobacter~~ anti-Enterobacter IgY has an unexpectedly  
good capacity to cure prematurely born newborn infants who  
have a very poor capacity to fight infections due to their  
immature immune system. The amount of gastric acid, which is  
an important factor in the protection against bacteria in the  
intestinal canal, is low in newborn infants. The unexpectedly  
good effect of the present invention is probably due to the  
relatively high pH in the stomach of the newborns, i.e.  
approximately 2-4. The normal pH of the stomach, i.e.  
approximately 1, would otherwise probably have inactivated the  
IgY.

Please replace the paragraph beginning on page 7,  
line 18, with the following amended paragraph:

The products and methods of IgY for prophylaxis or  
treatment according to the present invention have also been  
working on patients suffering from temporary immunodeficiency,  
e.g. immunosuppressed patients with leukaemia have been  
treated successfully with anti-candida IgY. Said

administration relates to oral application in order to prevent or treat oral and pharyngeal candidiasis infections caused by ~~Candida albicans~~ Candida albicans. Said type of administration for the purpose of preventing or treating oral and pharyngeal infections is disclosed in an another application filed previously by the same inventors is not part of the subject-matter of the present invention. However, early studies of administering ~~anti-candida~~ anti-Candida IgY to immunosuppressed patients in order to remove ~~candida~~ Candida from the gastrointestinal canal in order to avoid enteric infections and infections in other parts of the body, such as the vagina, seems promising. In order to treat enteric infections, as in the case of anti-~~Enterobacter~~ Enterobacter IgY, the ~~anti-candida~~ anti-Candida IgY needs to be buffered or combined with a nutritional agent according to the present invention, if not administered to a newborn or a prematurely born infant. Thus, the present invention also relates to prophylaxis or treatment of patients with temporary immunodeficiency and immunodeficiency diseases such as AIDS.

**Please replace the paragraph beginning on page 8, line 3, with the following amended paragraph:**

~~Enterobacter cloacae~~ Enterobacter cloacae isolated from faeces of infected newborns was used in an in vitro experiment to demonstrate the prophylactic potential of egg

immunoglobuline isolated from domestic hens hyper-immunised with ~~Enterobacter cloacae~~ Enterobacter cloacae antigen.

Please replace the paragraph beginning on page 8, line 12, with the following amended paragraph:

A suspension of formalin-killed ~~Enterobacter cloacae~~ Enterobacter cloacae was washed in saline and freeze-dried in ampoules;  $2.0 \times 10^8$  bacterial cells per ampoule. Twice a week, inoculations were carried out intramuscularly in domestic hens, using 1.0 ml purified water to resuspend each ampoule. Yolks of eggs collected from hyper-immunised hens were assayed to determine peak antibody titre using an ELISA (enzyme linked immunosorbent assay) specific for ~~Enterobacter cloacae~~ Enterobacter cloacae IgY.

Please replace the paragraph beginning on page 8, line 19, with the following amended paragraph:

After 3 to 4 weeks, when peak titre had been achieved, egg yolks were harvested by separation from the egg white and removing the contents of the yolk sac using a hypodermic syringe. The immunoglobuline fraction was purified using an industrial standard of supercritical CO<sub>2</sub>-equipment to dissolve the lipid. Leaving the proteinaceous polyclonal immunoglobuline in a purified state. The immunoglobuline fraction was diluted using distilled water to a concentration

of 10 mg/ml and lyophilised in trays. This solution was used to evaluate the prophylactic potential of the anti-~~Enterobacter~~Enterobacter IgY indicated below in the example *Treatment of newborn infants with anti-Enterobacter IgY.*

**Please replace the paragraph beginning on page 9, line 22, with the following amended paragraph:**

Infections caused by ~~Enterobacter chloaceae~~  
Enterobacter chloaceae are extremely dangerous for prematurely born infants. According to the literature 20 - 50% of premature babies of this weight, who gets an infection with ~~Enterobacter chloaceae~~ Enterobacter chloaceae, will die or get severe sequels.

**Please replace the paragraph beginning on page 9, line 27, with the following amended paragraph:**

In the experiment anti-~~Enterobacter~~Enterobacter IgY was used to treat prematurely born infants of less than 2500g, who have been infected by ~~Enterobacter chloaceae~~ Enterobacter chloaceae. Ten infants were daily given IgY with a high specific titre against ~~Enterobacter~~ Enterobacter in human breast milk. The treatment started as soon as a culture from stools or blood had been positive for ~~Enterobacter chloaceae~~ Enterobacter chloaceae. In nine of these patients Enterobacter chloaceae ~~Enterobacter chloaceae~~ was eradicated from their

stools. Only one patient, who already had a bacteraemia with Enterobacter ~~Enterobacter~~ before the treatment started, continued to have stool and blood cultures positive for Enterobacter ~~Enterobacter~~ for nearly a month. None of the patients died and none of them got any sequel. None of them developed any allergy to eggs.